K121493(1/2)
JUN 20 2012

SECTION 5: SPECIAL 510(K) PREMARKET NOTIFICATION

Summary of Safety and Effectiveness information

Tornier Inc. Ascend Shoulder System

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) **Device name**
Trade name: **Ascend Shoulder System**
Common name: Shoulder Prosthesis

Classification Number/ Classification name/Product code:

- Shoulder joint metal/polymer non-constrained cemented prosthesis are class II devices under 21 CFR 888.3650 (product code KWT) and are classified by the Orthopedic Devices Panel
- Shoulder joint metal/polymer semi-constrained cemented prosthesis are class II devices under 21 CFR 888.3660 (product code KWS) and are classified by the Orthopedic Devices Panel
- Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis are class II devices under CFR 888.3690 (product code HSD) and are classified by the Orthopedic Devices Panel

2) **Submitter**
Tornier Inc.
7701 France Avenue South; Suite 600
Edina, MN 55435
Registration Number: 9100540

3) **Company contact**
Brahim Hadri
Sr. Regulatory affairs Specialist
7701 France Avenue South, Suite 600
Edina, MN 55435 USA
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Email: bhadri@tornier.com

4) **Classification**

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWT; KWS; HSD;

5) **Legally Marketed Device to which Equivalence is Claimed:**

- **Primary Predicate:** Tornier Ascend Shoulder System: **K120794**

6) **Device description**

The Ascend Shoulder System consists of a humeral stem Titanium Plasma Spray (Ti PS) coated and un-coated stem versions, a mating humeral head and an optional all polyethylene glenoid. The stem and head may be used alone, as a hemiarthroplasty if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total shoulder replacement system.

The present device submission corresponds to changes made to the version of the device cleared in 510(k) K120794.

7) **Indications for Use**

The Ascend Shoulder System consists of a humeral stem (offered in two versions: Titanium Plasma Spray coated and un-coated version), a mating humeral head, and an optional polyethylene glenoid. The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement. The Ascend Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain.

The Ascend Shoulder System is indicated for use as a replacement of shoulder joints disabled by:

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

All components are single use. The humeral stem is intended for cemented or cementless use, while the all polyethylene glenoid is intended for cemented use only.

8) **Summary of technologies**

The modified Ascend Shoulder System was subjected to non-clinical testing (coating validation). The results of these non-clinical tests allow us to conclude that the Ascend Shoulder System described in this submission is substantially equivalent and as safe and effective as the original device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Tornier, Inc.
c/o Mr. Brahim Hadri
Senior Regulatory Affairs Specialist
7701 France Avenue South, Suite 600
Edina, MN 55435

JUN 2 0 2012

Re: K121493
Trade/Device Name: Ascend Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT, HSD
Dated: May 21, 2012
Received: May 21, 2012

Dear Mr. Hadri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121493
Device Name: **Ascend™ Shoulder System**

Indications for Use

The Ascend Shoulder System consists of a humeral stem, a mating humeral head, and an optional polyethylene glenoid. The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement. The Ascend Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain.

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All components are single use. The humeral stem is intended for cemented or cementless use, while the all polyethylene glenoid is intended for cemented use only.

Prescription Use ____X_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121493